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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,998	09/14/2000	Michael Berthon Jones	3869/10	8889

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/661,998

Applicant(s)  
Berthon-Jones

Examiner  
Joseph Weiss

Art Unit  
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 15, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-42 set forth in there base claims a “respiratory phase” which is understood in the art to be “inspiration, expiration, intervening pause or post-expiration/pre-inspiration.” However applicant goes on to claim “the phase” in claims 11, 16, 27 & 32 and then setting forth that “the phase” is quantified by a fraction of a “revolution” and in claims 27 & 32 applicant sets forth “the phase” as being “inspiratory” or “expiratory” and then the phase being “X decimal of a revolution” however outside of tracking this same claim language in the written description, applicant’s written description is devoid of any disclosure of establishing or equating any range of revolution values to being indicative of a commonly understood in the art “respiratory phase.” Accordingly, this aspect of the invention is not described in the written description in such a way as to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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(By dint of the doctrine of claim differentiation where expressly using inspiration and expiration in claims 16 & 32 is indicative that applicant's usage of "respiratory phase" is not referring to "respiratory phase" in its commonly accepted art specific manner and but to mean decimals of revolutions and by reading the claims in light of the written description where by not disclosing to the level of one of ordinary skill in the art the correlations between these fractions of revolutions and the commonly accepted usage of the term "respiratory phase" applicant means some sort of calculation "phase" terminology.)

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "respiratory phase" in claims 1-40 are used by the claim to mean "some fraction of a revolution (of a flow generation device???)", while the accepted meaning is "inspiration, expiration, intervening pause or post-expiration/pre-inspiration."

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999

(AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-2, 9-10, 17-34 & 37-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Banner et al (US 6390091).

In regards to claims 1, 17, 33 & 37, Banner discloses an apparatus for providing synchronized ventilatory support to a patient comprising at least one sensor to generate a respiratory effort signal (100), at least one sensor to generate a respiratory air flow signal (90); a processor for analyzing both respiratory air flow and the effort signal (60/62) which is fully capable of and does determine the instantaneous respiratory phase of a patient and generates a pressure request signal as a function of said instant phase and a ventilation pressure amplitude (see generally figs 3-8 and supporting text and & Figs 11-12 and supporting text) and a servo-controlled blower (20) to provide pressurized air to a patient in accordance with the pressure request signal.

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In regards to claim 2, 18, 34 & 38, Banner discloses the use of an esophageal pressure effort sensor (100, see fig 10) which are fully capable of being operated to be “independent of leaks in airflow.”

In regards to claim 9 & 25, Banner discloses delivering ventilation with a maximum and non-zero minimum value range (Col. 7 line 65 to the end of the col) which is indicative of pressure amplitudes (note correlation of work of breathing values to pressure and flow)

In regards to claim 10 & 26, Banner discloses the calculation/generation of a desired pressure request signal, including an error value that is a function of a difference between calculated/sensed ventilation and desired to targeted ventilation. (See col. 5 lines 15-27)

In regards to claims 19-32 & 39-40, the processor of Banner is fully capable of evaluating fuzzy inference rules related to various signals that are indicative of different aspects and parameters of pressure and ventilation in order to operate and control the system in response to the pulmonary needs of a user.

In regards to claims 27 & 32, while being parallel to the indefinite claims 11 & 16 have been rejected purely based upon the fact that in interpreting the claims the language present in these apparatus claims that parallels the indefinite language of claims 11 & 16 does not positively recite any structure or function or intended result or use or purpose that bring in by implication any structure, but merely present rules that any processor could evaluate, accordingly they can be rejected because they are not positive recitations that further limit the invention.

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In regards to claims 41 & 42, Banner discloses a device that practices a commensurate method wherein the instantaneous respiratory breathing phase is a fraction of the complete respiratory cycle. (Note figs 8-9 and supporting text).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-8, 11-16 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banner in view of Schmidt (US 6186142).

In regards to claims 3-8, 12-15, 35-36, Banner substantially discloses the instant application's claimed invention to include the utilization of standard rules/algorithms in an "if--then" format (see figs 3-7 & 11-12) for evaluating respiratory signals, but does not explicitly disclose utilizing Fuzzy logic to evaluate respiratory signals. However, Schmidt disclose such (See figs 3-4, note col. 12 line 50-col. 13 line 60, specifically col. 12 lines 52-55). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Schmidt and used them with the device of Banner. The suggestion/motivation for doing so would have been because standard algorithmic if --then

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formats are interchangeable with fuzzy logic algorithmic formats (See Schmidt col. 12 lines 52-55). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 11 & 16, the claims are indefinite to the point that it is not possible to examine the claims on the substantive merits and apply prior art to make a determination of patentability.

***Response to Arguments***

10. Applicant's arguments filed 15 Jan 03 have been fully considered but they are not persuasive.

NOTE generally:

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111© because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.



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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

NOTE Specifically:

In regard to the 35 USC 112 rejections applicant's amendment is proper and responsive, and resolves the rejections in part. Those rejections resolved are removed as reflected above, but the other rejections are retained as noted above with are response to the arguments below.

As noted previously, applicant's use of the RESPIRATORY ART SPECIFIC phrase "respiratory phase" in the claims is indefinite. The examiner concurs with applicant's definition and usage of the term "Phase" and if such terminology was used in the claims in accordance with the written description and the definition the 112 issue would be resolved. However, applicant does not do such. The technical usage of "phase" as set forth in applicant's written description does not support the usage of the RESPIRATORY ART SPECIFIC phrase of "respiratory phase" in the claims. Language to the affect of "determining an instantaneous phase of respiration" when read in light of the written description would be understood to mean what applicant is attempting to claim, but when claimed as "determining the patient's instantaneous respiration phase" does not comport with the written description, but conflicts because of the RESPIRATORY ART SPECIFIC meaning one of skill attaches to the phrase "respiration phase".

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In regards to the 35 USC 102 & 103 rejections, applicant's amendment is proper and responsive, but does not resolve the rejection, therefore the rejections are retained.

Regarding applicant's assertion that Banner does not utilize both respiratory air flow & respiratory effort, please note that banner utilizes "Work of breathing" which encompasses and utilizes both these respiratory parameters & variables. Hence applicant argues that such is a patently distinct difference is in error. (Please review Banner and also applicant may wish to review Bonassa which both disclose the definition and respiratory parameter components of work of breathing.)

The activation/actuation or "triggering" of ventilatory support is based upon work of breathing, which is based upon both respiratory flow & effort. Hence it meets applicant's limitations. Please note that respiratory effort is commonly measured in terms of pressure, hence an argument based upon the labels of "pressure" vs "effort" is not persuasive unless the pressure being measured is one that is not indicative of effort, which is not the case in Banner.

Regarding applicant's assertion that Banner does not disclose an "esophageal pressure effort sensor." Applicant discloses such as being "a pressure transducer implanted in the chest." (Page 10 lines 12-18 of written description). Banner discloses a pressure sensor that is implanted in the chest. No additional structural differences/distinctions attach to the pressure transducer when the label "esophageal" is used to set forth the transducer. Hence the reference meets the limitations as set forth by applicant.

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In response to applicant's arguments, the recitation "leak independent" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that "leak independence of the sensors" , a recitation of the intended use/results of the claimed invention must result **in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.** If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's argument that representing respiratory effort as a "fraction of a revolution" , a recitation of the intended use/results of the claimed invention must result **in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.** If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the

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intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's argument that "processor evaluates fuzzy inference rules" , a recitation of the intended use/results of the claimed invention must result **in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.** If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant is not positively claiming a microprocessor programmed with applicant's fuzzy logic rules.

### ***Conclusion***

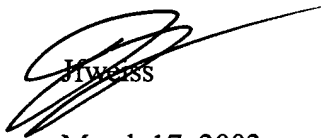
11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Aaron Lewis, can be reached at telephone number (703) 308-0716. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. F. Weiss, Jr.

March 17, 2003



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